UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,675	07/18/2003	Robert De Leys	2551-124	8086

23117 7590 02/22/2006

NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
LUCAS, ZACHARIAH	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/621,675	DE LEYS, ROBERT	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *23-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 08/146,028.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 22-26, 28-33, 35, and 36 (in part), drawn to an HCV Core peptide, and compositions thereof, classified in class 514, subclass 2.

II. Claims 22-26, 28-33, 35, and 36 (in part), drawn to an HCV NS4 peptide, and compositions thereof, classified in class 514, subclass 2.

III. Claims 22-26, 28-33, 35, and 36 (in part), drawn to an HCV NS5 peptide, and compositions thereof, classified in class 514, subclass 2.

IV. Claims 27 and 34 (in part), drawn to a method of detecting anti-HCV antibodies comprising the use of HCV Core peptides, classified in class 435, subclass 7.1.

V. Claims 27 and 34 (in part), drawn to a method of detecting anti-HCV antibodies comprising the use of HCV NS4 peptides, classified in class 435, subclass 7.1.

VI. Claims 27 and 34 (in part), drawn to a method of detecting anti-HCV antibodies comprising the use of HCV NS5 peptides, classified in class 435, subclass 7.1.

For Groups I and IV above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-VI, and, if one of Groups I or IV is elected, then election is also required to one of subgroups (A)- (J). Subgroups (A)-(J) represent the elected invention wherein the claimed peptide comprises one of the following Core epitopes:

(A) 1A, (B) 1B, (C) 2, (D) 3A, (E) 3B, (F) 3C, (G) 4A, (H) 4B, (I) 5A, or (J) 5B.

The indicated epitopes and the peptides corresponding thereto are defined in Table 9 of the application.

For Groups II and V above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-VI, and, if one of Groups II or V is elected, then election is also required to one of inventions (K)- (P). Subgroups (K)-(P) represent the elected invention wherein the claimed peptide comprises one of the following NS4 epitopes:

(K) 1, (L) 2A, (M) 2B, (N) 3A, (O) 3B, or (P) 4.

The indicated epitopes and peptides corresponding thereto are defined in Table 10 of the application.

For Groups III and VI above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-VI, and, if one of Groups III or VI is elected, then election is also required to one of inventions (Q)- (W). Subgroups (Q)-(W) represent the elected invention wherein the claimed peptide comprises one of the following NS5 epitopes:

(Q) 1A, (R) 1B, (S) 2, (T) 3, (U) 4, (V) 5, or (W) 6.

The indicated epitopes and peptides corresponding thereto are defined in Table 11 of the application.

The inventions are distinct, each from the other because of the following reasons:

2. The inventions of subgroups (A)-(W) and the inventions of Groups I-III or IV-VI are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. See MPEP § 806.05(d). In the instant case, each of the claimed peptides, or methods of use thereof, has separate utility as an antigen for the detection of anti-HCV antibodies, or (for the products claims) for the induction of an anti-HCV immune response. Each of these inventions is drawn to a different epitope or protein, which has s distinct sequence and structure from the other epitopes or proteins, or to methods of using such distinct epitopes or proteins. Therefore, subgroups (A)-(W) are distinct one from another, Groups I-III are distinct one from another, and Groups IV-VI are distinct one from another.

3. The inventions of Groups I-III are related as products and processes of use with the methods of Groups IV-VI. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the claimed products may be used in the claimed method for the detection of anti-HCV antibodies, or for the induction of an anti-HCV immune response. The products are therefore distinct from the claimed methods of use.

Species Election

4. This application contains claims directed to the following patentably distinct species of the claimed invention:

In addition to the elections of Group I-VI and Subgroups (A)-(W) above, the Applicant is additionally required to elect one of species (i)-(iii) and one of species (a)-(e).

Species (i)-(iii) represent the elected invention wherein the peptides have been biotinylated at the (i) N-terminus, (ii) C-terminus, or (iii) internally.

Species (a)-(e) represent the elected invention wherein the Y linker is chosen from (a) glycine residues, (b) beta-alanine, (c) 4-aminobutric acid, (d) 5-aminovaleric acid, or 9e) 6 aminohexonic acid.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 23, 27, 27, and 34 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Examiner's Notes

5. It is noted that in claim 23, the application purports to refer to the sequence DVKFPGGGQ as SEQ ID NO: 199. However, in the provided sequence listing, this peptide is identified as SEQ ID NO: 198. If a Group corresponding to this peptide is elected, the claim will be rejected as indefinite as it is not clear which peptide is intended to be claimed.

Conclusion

6. Because these inventions are distinct for the reasons given above, and because the literature and sequence searches required for any one of the groups is not required for the others, restriction for examination purposes as indicated is proper.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

2/20/06

JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600